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June 10, 2020

### **VIA ECF**

Honorable Joel Schneider  
United States Magistrate Judge  
U.S. District Court - District of New Jersey  
Mitchell S. Cohen Building & US Courthouse  
1 John F. Gerry Plaza, Courtroom 3C  
4th and Cooper Streets  
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION  
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Plaintiffs respectfully submit this response to Defendants' letter brief of May 27, 2020 requesting modifications to search terms. Since the filing of the brief, Plaintiffs have tried to meet and confer with each of the Defendants to reach agreement on reasonable modifications to the search terms, including proposing unilateral modifications to address Defendants' stated concerns in order to move the dialogue forward. Unfortunately, while Plaintiffs have made progress to the point of reaching agreement with ZHP as to modifications applicable to the US custodians, we have not been able to even commence meaningful negotiations with the remainder of the Defendants.

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It is clear that based on the limited information obtained during the meet and confer process none of the Defendants remaining at issue who joined in the request for relief set forth in Defendants' May 27 brief (Mylan, Teva, Torrent, Aurobindo, and Hetero) have met the good cause standard clearly articulated by the Court.

**A. Background**

As the Court is well aware, in the months leading up to the December status conference, per the Court's instructions, Plaintiffs, in good faith, and over many weeks, negotiated search terms with Defendants. Although Plaintiffs stressed the need for Defendants to load and sample custodians and provide test reports during those negotiations, Defendants elected not to do so.<sup>1</sup> Ultimately, the parties were able to agree to search terms, modifiers, and a procedure for addressing discrete issues that might arise, as evidenced by the agreed to order entered by this Court.

The Court was very clear that it wanted the search terms issues resolved by December, including presenting any disagreements to the Court for resolution at the December status conference. Defendants' refusal to conduct test collections and searches in November and December, and the ongoing delays in doing so, followed by a failure to follow the agreed to and ordered procedure, including the requirement in the ESI protocol to de-duplicate the documents when searching, and the proposed wholesale revision to the agreed to search terms in March, is what has led to the situation Defendants find themselves in now, in June. A situation of their own making.

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<sup>1</sup> Although Defendants claim they could not because the parties had not yet agreed to custodians, at the very least Defendants could have collected and loaded for sample purposes the custodians *they, themselves, proposed* in September 2019.

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**B. Individual Defendants**

**1. ZHP**

Despite joining Mylan's brief, ZHP has taken steps toward following the iterative process agreed to by the parties and ordered by the Court in December. ZHP has loaded and begun review of documents from the US entities based upon undisputed search terms. Although somewhat delayed to begin with, Plaintiffs and ZHP, over numerous meet and confers, exchanges of data, and proposed changes back and forth, have agreed to discrete modifications to primary search terms and modifiers applicable to the US based custodians. Plaintiffs have been informed that due to delays imposed by COVID-19, ZHP is still in the process of loading data from its Chinese custodians, but given the experience with ZHP through the iterative process of negotiating modifications to date, Plaintiffs are hopeful that they can similarly negotiate search terms applicable to the Chinese custodians, taking into account the Court's clear admonitions that the deadlines to produce the documents will not be extended. It is Plaintiffs' understanding that as a result of these meet and confers and the agreement reached, ZHP is not requesting the Court order the proposed modified search terms contained in the May 27, 2020 brief be applied to its custodians. Instead, the agreed to modifications will be implemented.

**2. MYLAN**

As a preliminary matter, it is important to note that it was not until after Mylan filed its brief on May 27, 2020, that Mylan finally actually began to attempt to follow the Court ordered protocol. As Mylan acknowledges, Mylan first contacted Plaintiffs in mid-January to discuss discrete issues related to the plaintiffs' custodial search terms that had arisen during the document collection process. Plaintiffs had a meet and confer call with Mylan on January 21, 2020. As

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Defendants further acknowledge, Plaintiffs readily agreed to certain changes proposed by Mylan, and Plaintiffs left the call with the understanding that Mylan was going to provide a concrete proposal with backup data for the other changes discussed on the call.

Mylan never complied with the ESI Protocol, having failed to load the documents onto its vendor's platform, de-duplicate, and email thread, so that useful data could be provided. Mylan's argument that it did not want to spend the necessary funds to do so does not hold any water in the face of a Court ordered ESI Protocol. As Mylan also acknowledges, instead of following the protocol ordered by the Court in December, Mylan spent the two months after initially contacting Plaintiffs working unilaterally to narrow the search terms and then presented Plaintiffs with a massive wholesale revision of the agreed to and ordered search terms, including elimination of entire categories of search terms ("we have also eliminated the authors and inspectors tab"), and radical modifications to other entire categories of search term ("other primary terms have been modified more broadly by amending the modifier terms where entire categories of modifiers are still being run against entire sets of primary terms, as well as by adding a proximity limitation").<sup>2</sup> Plaintiffs responded the same day stating Plaintiffs' position that a wholesale revision of the agreed search terms was not appropriate, especially where the issues were being raised so late in the process, but that Plaintiffs were still willing to meet and confer as we believed the Court would expect us to do so regardless of the facial impropriety of the request.

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<sup>2</sup> One example of the problems with Mylan's revised search terms proposal that made it impossible to work off of was Mylan's wholesale application of proximity modifiers to virtually all terms. So, for example, if a PowerPoint had a title "Valsartan Process" and a subsequent slide did not mention Valsartan but did discuss "contamination," a proximity search would not hit on that document. Similar issues also would arise with words in filenames or filepaths but not in the text of the documents.

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In the course of further back and forth communications, Plaintiffs e-mailed Mylan on March 26, 2020, and requested additional information needed to understand the purported basis for Mylan's request. In response, on March 31, 2020 Mylan only provided a "redline" intended to contrast their proposal against the ordered search terms. This redline was very difficult to decipher because it did not actually track the format of the ordered search terms.

On April 15, 2020 Mylan provided two spreadsheets containing raw hit counts for the ordered terms and Mylan's revised proposal. These, again, were not very helpful, as they were run without any attempt at determining unique hits (that is, the number of hits that did not already hit another term), and prior to any de-duplication and e-mail threading having been performed, significantly inflating the total number of documents and gigabytes of actual unique documents that would have to be reviewed. Mylan continued to ignore the remainder of Plaintiffs' data requests from their March 26, 2020 e-mail, which Plaintiffs again re-iterated to Mylan was necessary to evaluate Mylan's request for modifications, and to be able to have an informed discussion.

Finally, on May 8, Mylan provided some more detailed information responsive to the questions Plaintiffs had been asking since mid-March. From that delay in responding, it appears that Mylan had not collected that information, which was basic and should have been provided with the initial request to modify the search terms, when Mylan first proposed the wholesale revision of the ordered search terms in March. To date, however, Mylan still has not provided explanation for why any specific modification it requests is appropriate or necessary, relying

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instead on raw numbers based on the wrong set of documents, and a sample set of just 12 search terms.<sup>3</sup>

What Mylan should have done, per the agreed to and ordered protocol, is involve Plaintiffs in the process from the initial meet and confer in January onwards so that the parties could have cooperatively determined reasonable modifications of the agreed to search terms in order to reduce the volume, if possible, while still ensuring that relevant documents were produced. In the intervening days since the brief was filed, after an initial meet and confer and review of the data provided by Mylan, Plaintiffs proposed a set of significant modifications on June 1<sup>st</sup>, including moving certain terms from being standalone to being run with modifiers, addition of proximity connectors to certain terms, removing certain terms completely, moving certain terms to the modifiers category, and making changes to certain modifiers. Defendants provided a revised data run with Plaintiffs' proposed modifiers, but that revised data contained some anomalies increasing hit counts, such as being run on a larger set of data and the addition of facility names and locations as initially agreed to in the search terms but apparently not run by Mylan, making comparison of the data sets difficult. Plaintiffs again met and conferred with Mylan on June 5<sup>th</sup> and suggested that the addition of those facility names may have resulted in false hits on signature lines or letterhead and asked Mylan to further look into that. Plaintiffs also proposed additional significant modifications after that discussion. Defendants have not yet substantively responded to the June 5<sup>th</sup> additional proposed modifications.

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<sup>3</sup> Further, when pressed, Mylan admitted that it had not discussed any of its proposed modifications with any actual custodians to see if any of them would be problematic.

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Unfortunately, while Plaintiffs have provided proposed modifications, Mylan has not responded in kind. This is, in part, due to the fact that any such modification negotiations are supposed to be an iterative process where proposed modifications are tested, reports generated, reviewed, subject to sampling where needed, and then additional changes tested based upon those results, which Mylan's posture has made impossible. Complicating this process is the fact that, unlike some other Defendants, who appear to have at least loaded a large subset of their data with a review vendor, Mylan still has not loaded *any* of its data in a platform with robust processing and review capabilities, other than the data for 12 sample terms, which Plaintiffs have already offered to modify. As a result of this, 1) Mylan's numbers are vastly inflated due to a lack of de-duplication and e-mail threading; 2) the parties have an inability to accurately determine the results of proposed changes (e.g. is a particular change that results in a significant decrease in document count only doing so because those documents had an enormous number of duplicates or is it a substantive change eliminating relevant documents?); and 3) Mylan has an inability to quickly and reasonably turn-around data regarding proposed changes and to easily and readily sample documents.

The one thing that has become clear through this process, however, is that Mylan cannot show good cause for the modifications it requests for multiple reasons, including those described above:

- a) It cannot show that it could not have done the type of analysis that it did between January and May on sample custodial sources prior to December;
- b) It cannot show that it complied with the iterative process agreed to by the parties and Ordered by the Court in December;

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- c) It cannot show that the numbers it projects as to costs are accurate as it has failed to actually follow all of the agreed to search terms (e.g. Mylan has previously stated that previous numbers did not account for the AND NOT <other drug names> excluder that was negotiated as part of the Court ordered search terms, which should eliminate a significant number of irrelevant documents);
- d) It cannot show that the numbers it projects as to costs are accurate as it has failed to follow the ESI protocol and both vertically and horizontally de-duplicate documents and enable e-mail threading, which should substantially reduce the total number of documents;
- e) It still has not provided justification for why the *specific* modifications it requests reduce the number of total documents without substantially eliminating relevant documents as previously addressed in detail in Plaintiffs' May 8, 2020 letter to Mylan (attached hereto as Ex. A) at pp.7-33. Rather, Mylan provides the Court with a wholesale proposed modification of terms and modifiers on a take-it or leave-it basis;
- f) Its sampling of terms, which is the same one it did a month ago, continues to be flawed because the 12 sample search terms for which Mylan provides detail are not shown to be representative of the remainder of the search terms sought to be modified, nor were they picked at random but were specifically picked because Mylan believed they were facially overbroad;
- g) It still has not shown why the number of documents being hit and the projected cost incurred is unduly burdensome and disproportional to the needs of this case, consisting

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of likely thousands of individual plaintiffs and hundreds of millions, at the very least, in damages;

- h) It still has not shown that there is no less intrusive method for reducing the cost of its document review (for example, using automation for initial privilege review combined with robust claw-back provisions); and
- i) It continues to refuse to load and begin review of even the documents responsive to the search terms that it does not dispute, further delaying its ability to timely produce documents and prejudicing Plaintiffs.

### 3. TEVA

As Defendants acknowledge in their brief, when Teva first approached Plaintiffs with a request to make discrete modifications to search terms in February, Plaintiffs met and conferred with Teva and readily agreed to certain modifications (*see* Def Brief at 6 [D.E. 445]). Then Teva, just like Mylan, ignored the Court ordered process and failed to continue any form of meet and confer. In fact, the first that Plaintiffs heard again from Teva regarding search term issues was *after* Defendants' brief was filed on May 27, and apparently only in response to *Plaintiffs'* e-mail suggesting a meet and confer sent on May 29. Further, despite the fact that Plaintiffs asked for the data and analyses contained in Defendants' brief in that same May 29 e-mail, it was not until June 8, just two days before Plaintiffs' reply brief was due, that Teva provided document hit counts to Plaintiffs, despite Teva having stated, under oath, that Teva's counsel had received a detailed hit report on the original search terms in February and multiple hit reports since that time (*see* Def Brief at Ex. E para. 4 [D.E. 445-5]). This lack of communication evidences a total disregard of the

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agreed to and Court ordered process set forth in December and, standing alone, should be enough to show that Teva cannot show good cause for the relief it now seeks.

However, even more egregiously, the hit reports finally provided by Teva show that Teva's numbers as to documents (and therefore projected costs) is severely inflated and completely unreliable. First, contrary to the agreed and ordered search terms, Teva ran *its own name* ("Teva") and related entity names as part of the Primary Entity Terms. This, alone, is responsible for well *over one million documents with families* in Teva's hit report. Second, despite the parties having clearly limited the Primary Economic Terms to solely the small number of economic custodians, Teva's vendor ran those terms across *all* custodians. These Primary Economic Terms, alone, represent *over two million documents with families*. While it is impossible to determine the exact impact of these two fundamental errors on the final unique document counts based upon the data available to Plaintiffs, it renders all of Teva's numbers presented to the Court, including but not limited to estimated costs, completely meaningless, and renders any attempt by Teva to show good cause as a result moot.

#### **4. TORRENT**

It was not until June 9, just one day before Plaintiffs' brief was due, that Plaintiffs heard from counsel for Torrent regarding search terms for the first time ever. Plaintiffs both spoke with counsel for Torrent that same day and then subsequently received hit counts and a report listing specific search term combinations that Torrent contended were problematic along with hit counts that night. Further, Torrent confirmed that, unlike Mylan, it had loaded and was in the process of further loading custodial data onto a review platform and was going forward with review and

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production of documents that were not on its list of potentially problematic search term combinations.

While all helpful, Torrent, again, should have done this months ago, and Torrent's failure to engage in a meet and confer process, alone, should be enough to defeat a showing of good cause. Further, the list of potentially problematic search term combinations provided by Torrent clearly shows a lack of good cause for this Court to order the modifications to the search terms actually proposed in Defendants' brief, which was based solely on Mylan's analysis of Mylan's documents from specific Mylan custodians and not Torrent's documents from its custodians, as applied to Torrent. Doing so would be like using a sledgehammer to hit a tiny nail. Instead of targeted modifications that address the specific issues identified by Torrent's vendor, the modifications proposed in Defendants' brief would result in wholesale revisions to terms that are *not* problematic when applied to Torrent, and a failure to modify specific terms that *are* problematic when applied to Torrent, but not actually addressed in the proposed modifications.

## 5. AUROBINDO

Plaintiffs conferred with Aurobindo's counsel in April-May regarding certain changes to the Other Drug Names and Facilities search terms and reached agreement. Plaintiffs did not hear further from Aurobindo's counsel until receiving a letter on June 8, and had a subsequent phone conversation. Although the June 8 letter provided some cost estimates from Aurobindo's vendor related to the US Aurobindo entities, it failed to provide any hit reports, or any substantiation for those numbers. The letter further failed to explain what, if any, steps Aurobindo had taken to determine how and whether the revised search term proposal requested by Aurobindo were tailored to reduce irrelevant documents while ensuring relevant documents were not eliminated as well. It

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was also clear from the letter and the subsequent meet & confer that Aurobindo's Indian entity has yet to begin any collection of custodial documents. Given the substantially incomplete data provided by Aurobindo, Plaintiffs submit that Aurobindo has not shown good cause for the relief it requests.

## **6. HETERO**

Plaintiffs have yet to hear from counsel for Hetero entities. Plainly, no good cause exists for any relief as to Hetero given the complete lack of contact or attempt to meet and confer.

### **C. COST SHIFTING**

Although Defendants (with the exception of ZHP, with whom Plaintiffs have resolved their issues as set forth above) ask this Court to impose cost-shifting to Plaintiffs, they base it on the false premise that "Plaintiffs have refused to meaningfully meet and confer regarding modifications to the Original Search Terms that would reduce that burden, [and thus] Plaintiffs should be required to shoulder a portion of the cost for all of the unnecessary processing, storage, and attorney review that will result" (Def Brief at p. 19 [D.E. 445]). As demonstrated above, however, that is the exact opposite of what has actually happened. It is *Defendants* who have failed to meaningfully meet and confer regarding search terms, starting in November 2019 when they chose not to sample custodians during the initial negotiation of search terms all the way through the filing of their brief. Further, Defendants' citation to case law is inapposite. For example, in *Costantino*, this Court refused to impose cost-shifting, but encouraged the parties to agree on a reasonable cost sharing arrangement where "*[p]laintiff's counsel has already indicated a willingness to share costs.*" *Costantino v. City of Atl. City*, 152 F. Supp. 3d 311, 336 (D.N.J. 2015) (emphasis added). In *Major Tours, Inc.*, defendants provided evidence that the e-mails

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sought were reasonably inaccessible (on backup tapes) and that the cost to access such information was high. This Court then cited to and analyzed the seven factor test articulated in *Zubulake*:

1. The extent to which the request is specifically tailored to discover relevant information;
2. The availability of such information from other sources;
3. The total cost of production, compared to the amount in controversy;
4. The total cost of production, compared to the resources available to each party;
5. The relative ability of each party to control costs and its incentive to do so;
6. The importance of the issues at stake in the litigation; and
7. The relative benefits to the parties of obtaining the information.

*Major Tours, Inc. v. Colorel*, No. CIV. 05-3091JBSJS, 2009 WL 3446761, at \*5 (D.N.J. Oct. 20, 2009), aff'd, 720 F. Supp. 2d 587 (D.N.J. 2010) (citing *Zubulake v. USB Warburg LLC*, 217 F.R.D. 309, 322 (S.D.N.Y.2003)). This Court concluded, based on its analysis of those factors and its experience with the case and the large number of custodial e-mails already produced, that the likelihood of additional non-cumulative documents existing on the backup tapes was low, and that therefore some cost-sharing was appropriate. In the instant case, Defendants have made no showing to support *any* of the seven factors articulated by this Court in *Major Tours*.

Plaintiffs respectfully submit that Defendants' request for cost-shifting should be denied.

**D. CONCLUSION**

Plaintiffs have reached agreement as to revised terms applicable to ZHP's US custodians, and will work to reach similar agreement with regard to ZHP's Chinese custodians, but with the understanding that the current schedules remain in place. Plaintiffs have also committed to continue working with all Defendants, in good faith, to address and modify search terms where Plaintiffs believe such modifications are reasonable, appropriate, and backed by data. Plaintiffs have no interest in having Defendants review and produce irrelevant documents, nor to slow down

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the entire discovery process. Plaintiffs, however, cannot simply agree to changes not supported by data, nor to remove terms and term combinations that are key to the litigation, simply for the purpose of lowering the overall volume of documents without regard to relevancy.

For the reasons detailed above, no Defendant has demonstrated good cause to require this Court to order that the modified search terms proposed by Defendants be applied to them. The Court made it clear that it intended to decide the search terms issue in December. Plaintiffs made repeated requests to Defendants for data that would allow Plaintiffs to negotiate modifications on allegedly problematic combinations of terms. Despite the Court's clear intention and Plaintiffs' willingness to engage, Defendants did not sample custodians and obtain data necessary to conduct a robust negotiation. Defendants *chose* not to. Then, even after the Court's Order in December, Defendants continued to not just delay their collection and processing of custodial documents, but to ignore the agreed to and Court ordered process and, instead, either unilaterally decided to modify the search terms on a wholesale basis without consulting Plaintiffs, or do nothing at all.

It is now June. Mylan still has not even loaded its custodial data to its review platform, much less begun review. Other Defendants have begun that process, but have now jumped on the Mylan massively overbroad modified search terms bandwagon without any real justification, based upon actual data, for doing so, other than simply lowering overall document counts. Making modifications to search terms solely for the purpose of lowering hit counts is extremely prejudicial to Plaintiffs and not an argument for proportionality, without more. Even Defendants have implicitly acknowledged that this is a large litigation and that the breadth of the search terms is reasonable, as evidenced by the agreed to order entered by the Court in December.

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Plaintiffs, therefore, respectfully request that the Court not just deny Defendants' request to modify the search terms as requested in their brief (subject to the agreed to modifications with ZHP), but further order that any future request by any Defendant for a Court order modifying search terms show not just good cause for the modification, but also specifically show that the particular Defendant could not have brought such request to the Court as part of this briefing. While Plaintiffs are willing to continue to work with Defendants in good faith to modify search terms as appropriate, Plaintiffs should not be forced to spend the extraordinary amount of time and effort that has been spent on their May 8 response letter, and this briefing, over and over again each time a Defendant wants to modify a term that Plaintiffs disagree should be modified. Plaintiffs would further request that the Court remind Defendants of their discovery obligations in that Defendants are obligated to suggest new or additional search terms or to reinstate removed terms should they come up as relevant in the course of their review or in interviews with their client or custodians. Modifications to search terms is not just a one-way street.

Thank you for your courtesies and consideration.

Respectfully,



ADAM M. SLATER

Cc: All Counsel of Record (via ECF)